UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt. 1:13-md-02419-RWZ
THIS DOCUMENT RELATES TO: All Actions	

LEAD COUNSEL'S MOTION FOR APPROVAL OF AGREEMENT BETWEEN THE TORT TRUSTEE AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES REGARDING RESOLUTION OF CLAIMS FOR REIMBURSEMENT OF HEALTH CARE COSTS

On July 28, 2016, Lead Counsel for the Plaintiffs' Steering Committee ("Lead Counsel") made a report to the Court concerning the status of claims processing and attempts by the Court-appointed Tort Trustee, Lynne Riley ("Tort Trustee"), with the aid of Lead Counsel and others, to resolve claims for medical cost reimbursement asserted against victims' recoveries from the Tort Trust in the NECC Bankruptcy Settlement by the Centers for Medicare and Medicaid Services ("CMS"). Lead Counsel reported that the Tort Trustee had reached an agreement in principle with CMS and that the draft agreement was under consideration by the United States Department of Justice ("DOJ"). Finalization and signature of that agreement awaits DOJ approval. A copy of the final draft agreement under consideration by the DOJ is attached hereto as Exhibit A.

The agreement provides tangible benefits to Claimants in the Bankruptcy Settlement. These include:

- The ability to resolve all claims by CMS for health cost reimbursement using a simple and easily administered formula;
- Utilization of criteria already approved by the Bankruptcy Court and already applied to each Claimant by the Court-appointed Claims Administrator to establish the total amount a Claimant would pay to resolve CMS's claim – from a

low of 10% to a high of 21.5% of their settlement payments – with only a handful of claimants paying more than 15%;

- A nine month limit (between September 1, 2012 and May 31, 2013) for Medicare eligibility of Claimants, outside of which CMS has agreed not to pursue claims for health cost reimbursement;

- A waiver by CMS of any potential claim against Claimants in the lowest injury category (Category VII);

- The ability to resolve Medicare's claim as well as claims for health cost reimbursement from many large insurers for the same percentage amount –rather than negotiate with two different lienholders;

- An ability, by the vast majority of Claimants, to opt-out of the resolution program and negotiate resolution of CMS's claims on their own if they so choose; and

- For those Claimants who seek to opt-out of the resolution program and negotiate CMS's claim individually, CMS will designate a special contact person at its Benefit Coordination & Recovery Center to negotiate CMS's claims.

Nothing in the agreement requires or suggests that while the agreement is pending approval by this Court or the DOJ CMS should refrain from providing information to Claimants or their attorneys concerning CMS's claim for medical cost reimbursement.

In the interest of expediting the necessary Court approval (and thus expediting payment to victims), Lead Counsel files this motion for approval of the agreement while formal approval of the terms of the agreement are still under consideration by the DOJ. This Court has set a telephonic hearing for August 16, 2016, at 2:00 p.m., to consider the agreement with CMS. We have invited representatives of CMS and DOJ to participate. A proposed order approving the agreement with CMS is attached hereto as Exhibit B.

I. The Tort Trustee's Obligations Concerning CMS Claims for Medical Cost Reimbursement

The Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [MDL Dkt. No. 1352-1] (the "NECC Plan") provides that the Tort Trustee is responsible for

all reimbursement and reporting obligations imposed by the Medicare Act[1] for repayment of any NECC related conditional payments made by CMS under Medicare Part A, B, C and D.[2] The Plan specifically provides that the Tort Trustee should attempt to enter into a global resolution with CMS to reimburse or otherwise resolve all Medicare claims for medical cost reimbursement as required by federal statute.[3] The Plan also provides that if a global resolution with CMS cannot be reached, before distribution of any funds from the Tort Trust to any Claimant, the Tort Trustee must, among other obligations, comply with all formal notice requirements under federal statute, provide notice of any potential CMS claim to the Claimant and, failing the Claimant's resolution of CMS's claim within 120 days of that notice, the Tort Trustee is obligated to ensure that CMS's claim is resolved before making payment to the Claimant. [4]

The purpose of entering into a global settlement with CMS is twofold. First, such an agreement provides administrative efficiencies. Under such an agreement a simple mechanism can be established to resolve each of CMS's claims for medical cost reimbursement without the time and effort involved in having each Claimant, their attorney, or a lien resolution professional individually negotiate with CMS. Such an agreement also alleviates the need for CMS personnel to search claims data on individual claimants and determine which services are related to injuries suffered from exposure to a NECC contaminated product and negotiate the proper amount of CMS's claim. This savings in time and effort directly translates into the second purpose of such a resolution – to pass onto the Claimant the savings that come from administrative efficiency. The money that would otherwise be used to accomplish individual resolution can instead be passed onto the Claimant in the form of higher settlement payments. The benefits of such a

[1] 42 U.S.C. 1395y(b) and 1995y(b)8.
[2] NECC Plan at 28-29.
[3] *Id*.
[4] *Id*.

global approach are well recognized and global resolution of Medicare's claims are a standard part of almost every MDL settlement involving personal injury claims.[5]

II. The Tort Trustee's Agreement with CMS

The agreement reached between the Tort Trustee and CMS (the "agreement"), if approved, would resolve the vast majority of claims for health care cost reimbursement by CMS. It would resolve CMS's claims for reimbursement for health care coverage provided to victims of the NECC outbreak paid for under Medicare Parts A and B from payments made to Claimants in each of the NECC National Settlement, the Insight Settlement, the Inspira Settlement, the Highpoint Settlement, and the Michigan Pain Specialist Settlement[6] (collectively, the "Five NECC Settlements"). The agreement is the result of extensive claims analysis and consultation among members of the PSC, a separate lien sub-committee, other plaintiffs' counsel, and the Tort Trustee. It is also the result of a great deal of negotiation with counsel for the DOJ and personnel from CMS over many months. At each step in the process, members of the negotiating team reached out to plaintiffs' counsel, particularly in states with large numbers of Claimants, to seek advice and counsel, to preview various portions of the agreement, and to ensure the agreement would benefit the largest number of Claimants possible.

[5] *See In re Oil Spill by Oil Rig Deepwater Horizon*, 295 F.R.D. 112, 160-61 (E.D. La. 2013) ("This global resolution program will, if achieved, provide an efficient way to protect the Medicare Program's interests in the settlement funds while also providing significant benefits to Class Members. . . .The global resolution approach has been successfully utilized in almost all MDL settlements involving personal injury claims since 2005.") (internal citations omitted).

[6] Payments from the MPS Settlement are not made by the Tort Trustee but rather by a separate MPS Settlement Fund Administrator. The MPS class action settlement was approved by a state court in Michigan after the Third Amended Plan of Reorganization was approved by the Bankruptcy Court. Lead counsel in the Michigan class settlement is a Court-appointed member of the PSC in the MDL. Michigan Class Counsel has been involved in the negotiation of the Agreement with CMS and has agreed to seek approval from the Court in Michigan of the Agreement for implementation in the MPS Settlement.

A. The Claim Resolution Matrix

Claimants who participate in the CMS claim resolution program pursuant to the Agreement will be able to resolve CMS's claim for reimbursement of health care costs using a simple formula. Attached as Exhibit C to this motion is a copy of the negotiated Claims Resolution Matrix. Under the Agreement, a Claimant participating in the resolution program would have a portion of each of his/her payments from each of the Five NECC Settlements deducted and paid to CMS. The amount deducted from each Claimant's payment is derived by reference to the Claims Resolution Matrix and range from 10% to 21.5%. If, for example, based on a Claimant's particular circumstances, the Claimant falls into a box on the matrix indicating his or her payment percentage is 10%, then 10% of each payment made to the Claimant by the Tort Trustee or the MPS Settlement Fund Administrator, whether from the National Settlement or one of the four clinic specific settlements, would be deducted and paid to CMS in order to resolve CMS's claim.

The Claims Resolution Matrix is based upon the criteria already approved by the Bankruptcy Court and used by the Court-appointed Claims Administrator to determine payments to Claimants in the NECC National Settlement. As the Court will recall, each Claimant applies for compensation using one of seven categories of injury as set forth in the chart below.[7]

Category	Description	Base Points
Category 1	Death after MPA Injection *and* (1) Spinal or Paraspinal Fungal Infection[8] and/or (2) Fungal Meningitis	55
Category 2	Non-Death Fungal Meningitis *and* Spinal or Paraspinal Fungal Infection after MPA Injection	40

[7] A more detailed description of each of the seven injury categories is provided in in the Court Approved Claims Resolution Procedures attached hereto as Exhibit D.

[8] Including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis.

Category 3	Non-Death Fungal Meningitis after MPA Injection	30
Category 4	Non-Death Spinal *or* Paraspinal Fungal Injection after MPA Injection	20
Category 5	Peripheral Joint Fungal Infection after MPA Injection	10
Category 6	Symptoms of Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness and/or Pain at Injection Site *and* a Lumbar Puncture, MRI or CT Guided Biopsy after MPA Injection	1
Category 7	No Symptoms or No Lumbar Puncture, MRI, or CT Guided Biopsy after MPA Injection	½

Each Claimant qualifying for one of the seven categories is awarded a base point amount, as indicated above, depending upon the category. Category I Claimants receive the highest number of base points and Category VII Claimants receive the lowest.

Within all injury categories (except for Category VII), Claimants can also apply for certain "upward adjustments" to their base points. These adjustments are meant to capture the differences in injury between individuals in the same injury category. Based on the number of base points awarded (depending on injury category) and the number of points awarded for all upward adjustments for which they qualify, the Claimant's total number of points is calculated and used as a basis for determining the total payment to the Claimant in the NECC Settlement. Each point is assigned a value based on the total number of points awarded to all Claimants and

the total amount available for distribution. The more points awarded, the higher a Claimant's total payment from the Tort Trust.[9]

The Claims Resolution Matrix also uses the Claimant's injury category (Categories I – VII) and the number of points awarded to each claimant for two of the "upward adjustments" to determine the percentage of the Claimant's recovery to be paid to CMS to resolve CMS's claim. In general, the higher the injury category and the higher the number of points awarded for the long term hospitalization adjustment ("LHA")[10] and for the long term antifungal treatment adjustment (LAFT),[11] the larger the percentage of their total recovery a Claimant will pay to resolve CMS's lien. For example, a Category III Claimant who was awarded 4 points for LHA and 3 points for LAFT would pay 12.5% of their total payments from all settlements to resolve CMS's claim.[12]

Of the many upward adjustments available to Claimants in the Court-approved settlement process, LHA and LAFT are most closely associated with higher medical costs. The longer an individual was hospitalized and the longer they were required to be treated with antifungal medication, the higher the medical costs associated with their care. This is not true of other upward adjustments available to Claimants (e.g. age, existence of dependent children, lost income). In this way, the Claims Resolution Matrix takes into account the higher costs associated with medical treatment provided to Claimants with more severe injuries. Claimants

[9] The procedures for each of the individual clinic settlements are similar. In some instances the procedures for determining points awarded in the clinic settlements are identical to those in the National Settlement. In some instances the clinic settlement procedures may include additional upward adjustments not available in the National Settlement.

[10] The LHA adjustment awards additional points to Claimants based upon the length of time they were hospitalized as a result of their exposure to an NECC contaminated product.

[11] The LAFT adjustment awards additional points to Claimants based upon the length of time they were treated with antifungal medication as a result of their exposure to an NECC contaminated product.

[12] A Claimant in Category III is required to pay 11.5% if they received anywhere from 2.5-5 points for long term hospitalization and are required to pay an additional 1% if they received anywhere from 2-5 points for LAFT (11.5% + 1% = 12.5%).

with higher awards for LHA and LAFT are generally awarded a greater number of points under the NECC Settlement procedures, and generally will receive the largest awards from the NECC Settlements. Use of these upward adjustments as a proxy for CMS's expenditures avoids the need for review of individual Claimant's medical records and negotiations over which services paid for by CMS are related to exposure to an NECC product.

B. The time period for which CMS will recover is limited

The Agreement provides that CMS will only seek to recover against those Claimants who were eligible for Medicare (due to age, disability or other reasons) during the period from September 1, 2012 to May 31, 2013. Any Claimant who participates in the resolution program and was not Medicare eligible during this time period, whether they later had medical services paid for by Medicare related to exposure to an NECC product or not, will receive the benefit of the release from CMS included in the Agreement – but will not be required to pay a percentage to CMS under the Claims Resolution Matrix. For example, any Claimant who became Medicare eligible after May 31, 2013, although they may have received medical care covered by Medicare, will pay nothing to CMS to resolve CMS's claim.

C. For Claimants with claims from multiple sources, the Claims Resolution Matrix may cap their liability

The preliminary data obtained by the Tort Trustee on the first 1199 fully approved claims and used, in part, to help develop the Claims Resolution Matrix, indicated that a high percentage of Claimants may be subject to a claim for reimbursement from both Medicare as well as from one (or more) private insurers.[13] The Tort Trustee, with assistance from Lead Counsel and others, has reached an agreement in principle to resolve the claims for reimbursement by some

[13] This may occur for several reasons. For instance, someone may have aged onto Medicare (and off a private insurance plan) while being treated for an NECC related illness. That individual would be subject to a claim for health care reimbursement from both his/her private insurer as well as CMS.

large private insurers on the same basis and using the same claims resolution matrix as preliminarily agreed to by CMS. The Agreement with CMS provides that in the cases where a Claimant has both a claim for medical cost reimbursement asserted by CMS and a private insurer who has agreed to participate in a similar arrangement, the percentage payment set forth in the Claims Resolution Matrix will represent a cap on the Claimant's liability. In those situations CMS has agreed to receive only 50% of the total payment called for by the matrix to resolve its claim. The other 50% would be used to satisfy the claim of the private participating insurer. The Claimant would thereby resolve both public and private claims for the same total deduction from their payment.

In situations where the Claimant has a claim for reimbursement from both Medicare and a private insurer with whom the Tort Trustee has no agreement, CMS has agreed to accept 50% of the total payment otherwise called for by the matrix to resolve CMS's claim. The Claimant and/or the Claimant's attorney would be responsible for resolving the remaining private claim through individual negotiations.

D. No Payment Will Be Made to Medicare by Category VII Claimants

Claimants in Category VII will not be required to make any payment to CMS under the Agreement. Whether or not they were Medicare eligible during the applicable time period, they will receive the benefit of the release by CMS under the Agreement with no payment to CMS.

E. The vast majority of Claimants in Categories I-VI will have the option to participate in the resolution program or to resolve CMS's claim on their own

During the negotiation of the Claim Resolution Matrix, Lead Counsel and others reached out to various plaintiffs' counsel with a large number of Claimants and asked them to evaluate the proposed matrix – particularly in terms of whether it would save their client's money when compared to resolution of outstanding Medicare claims on an individual basis. The response was

overwhelmingly positive. However, during this process some counsel expressed preference for the ability to resolve their client's claim, in particular situations, on an individual basis through individual negotiation. To that end, the Agreement provides that all Claimants who are in Categories I-V in the National Settlement have the option to inform the Trustee that they do not wish to participate in the resolution program. Once a Claimant exercises this opt-out right, he or she (or his or her attorney) can individually negotiate with CMS to resolve the claim with respect to all payments from any of the NECC Settlements. This same opt-out right is also afforded to Claimants in the Insight Settlement who are in Category VI.[14]

Claimants in Category VI would also have the opportunity to opt-out of the Agreement and pursue individualized negotiations in the situation where they also have a claim for reimbursement from a state Medicaid agency, the Veteran's Administration or TriCare . For those Category VI Claimants who do not have a claim from one of these other sources and therefore are not able to opt-out, the percentage of recovery paid under the matrix is the lowest – 10%. Given the average estimated payments to Category VI claimants in the National Settlement, the impact of this payment is minimal. The average number of total points awarded to Category VI claimants in the National Settlement is 1.5. Thus, the average amount deducted from the Initial Payments made to Category VI claimants in the National Settlement and paid to CMS under the resolution plan approximately $130.

[14] Because of the procedures for awarding points in the Insight Settlement differ from those in the National Settlement, Claimants in Category VI in the Insight Settlement, in some instances, are receiving substantial awards and thus, would pay substantially more than other Category VI claimants to CMS under the resolution plan. For instance, the Insight Settlement Procedures take into account lost wages. In some instances individuals in Category VI in the Insight Settlement, although receiving few "base points," are receiving substantially more points as a result of lost earnings and might, in some circumstances, pay a disproportionately higher amount to resolve their liens than a Category VI Claimant in the National Settlement. In consultation with counsel for Virginia Claimants it was determined that in order to accommodate these situations, claimants in Category VI in the Insight Settlement should also have the ability to opt-out of the Agreement and resolve CMS's claim individually if they so choose.

III. The Court Should Approve the Agreement with CMS

Lead Counsel, the PSC, and the Tort Trustee urge the Court to approve the proposed Agreement with CMS. The Agreement absolves each Claimant, their attorney, and the Tort Trustee of the statutory reporting obligations imposed by Section III of the Medicare, Medicaid & SCHIP Extension Act of 2007[15] and affords Claimants a simple and quick mechanism to resolve CMS's claims for health care cost reimbursement without further negotiation and on a very favorable basis. For the vast majority of Claimants, and for all the Claimants in Categories I-V who suffered the most serious injury, the resolution offered by the Agreement is wholly voluntary. If for some reason, in a particular situation, the Claimant or their attorney feels that they can negotiate a better deal with CMS, they have the right to opt-out of the Agreement and immediately engage in individual negotiations with CMS to resolve CMS's claim.

During the negotiation process the Claims Resolution Matrix was tested by plaintiffs' counsel from almost all affected states. Counsel with the ten greatest number of clients approved for payment by the Claims Administrator were asked to run their client's potential claims and compare them to the result obtained by use of the proposed matrix. The response was positive and very few instances were identified where application of the matrix did not result in a very favorable resolution for the Claimant.

[15] 42 USC §1395y(b)(8).

For the reasons set forth above, Lead Counsel respectfully requests that the Court enter the attached proposed Order approving the Agreement reached between the Tort Trustee and CMS.

Dated: August 4, 2016

Respectfully submitted,

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: August 4, 2016

/s/ Thomas M. Sobol
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